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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/785,162

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BIO-5042

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EXAMINER

LEACH, CRYSTAL I

ART UNIT

PAPER NUMBER

3737

MAIL DATE

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10/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/785,162	Applicant(s) GOVARI ET AL.	
	Examiner CRYSTAL I. LEACH	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-24, 35-37, 39-42, 44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-24, 35-37, 39-42, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/20/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

1. Applicant's arguments with respect to claim 1-16, 18-24, 35-37 and 39-45 have been considered but are moot in view of the new ground(s) of rejection.

DETAILED ACTION

Information Disclosure Statement

2. The Information Disclosure Statements (IDS) submitted on September 20, 2007 is in compliance with 37 CFR 1.97 and 1.98. The references therein have been considered.

Claim Objections

3. Claims 1-16, 18-24, 35-37 and 39-45 objected to because of the following informalities: Claims 1, 6, 7, 12, 13, 18, 35 and 39 all refer to "six dimensions of location and orientation". Examiner believes that applicant is referring to --six degrees of location and orientation--. The written description also refers to "six dimensions of location and orientation". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding independent claims 1 and 7, applicant indirectly places limitations on subject matter that is not distinctly claimed. Specifically,

Art Unit: 3737

claim 1 states "An apparatus for use with a steerable catheter...the apparatus comprising a robot, comprising...". It is unclear whether the applicant intends to claim an apparatus capable of being used with a steerable catheter, a robot comprising the listed limitations or a steerable catheter. Similar reference is made to independent claim 7.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4,6-10,12,18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green (5,808,665) in view of Webster (6,123,699).

Green discloses an apparatus and method for use with a steerable catheter (268R, 268L; col. 10, lines 47-61) with hand controllers (72R, 72L) and a deflectable distal tip. Green discloses an end-effector (170, 270R, 270L; col 2, lines 3-7) that moves in response to the hand-operated control means (col 9, lines 10-21). Green discloses use of a servomechanism that includes computer (42) that is well known in the robotic art (col 11, lines 44-47). Green discloses the control section as containing motors and linkages which operate the insertion section with five or more degrees of freedom (abstract, lines 12-14) and is also capable of pivoting with one or more degrees of freedom (abstract, lines 18-20). This would encompass the six dimensions of position and orientation information of the present invention. Green discloses pivotal movement

Art Unit: 3737

of the distal tip in any direction, which would include rolling or jiggling, as well as axial movement of the outer section (150L2) into and out of the inner section (150L1) as well as rotation about the longitudinal axis (col 8, lines 58-66). Green does not disclose a thumb control explicitly.

Webster discloses sliding a button longitudinally in the length of a slot by means of thumb pressure within a control handle (col 8, lines 40-42).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to combine the steerable catheter assembly of Green with the thumb control of Webster for the purpose of manually manipulating the catheter tip in a desired path.

7. Claim 5,11,13-16,35-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green (5,808,665) in view of Webster (6,123,699) and Vesely (6,246,898).

The modified invention of Green discloses the invention substantially as claimed except for the apparatus comprising a computer pointing device and a position sensor, wherein the controller is adapted to receive the position signal.

Vesely discloses a steerable catheter with position tracking and method for using (abstract, lines 2-6) and a computer pointing device (col 25, lines 59-63), wherein a robotic controller receives the position signal and responds thereto (col 26, lines 41-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to have combined the modified steerable catheter of Green with the position tracking, computer pointing device, and robotic control of Vesely for the

purpose of providing more accurate guided therapies.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-16, 18-24, 35-37 and 39-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plicchi et al. (US 2004/0254566) in view of Funda et al. (5,417,210) or Stevens-Wright (5,383,852).

Plicchi et al teach a robotic system remotely controlled by a user, wherein the system maneuvers and positions a flexible catheter in a body (see abstract). Plicchi et al. teach that the catheter tip is deflectable and rotatable (see) and that the catheter's position can be viewed on a monitor in real time (see fig. 1-3 and 7 and para. [0016]; [0032]; [0034]; [0035]; [0036], l. 1-3).

Plicchi et al. do not teach that the control is a thumb control or a position sensor located at the distal tip of the catheter.

Funda et al. teach a robotic system for steering and manipulating a catheter wherein the controller is a joystick (see col. 4, l. 21-30 and col. 6, l. 32-59). It would be obvious to one of ordinary skill in the art that the joystick can be moved with a thumb in order to control the steering or maneuvering of the catheter. Funda et al. also teach a position sensor located in the distal tip of the catheter (see col. 5, l. 51-57 and col. 6, 25-

Art Unit: 3737

31). Funda et al. also teach that the catheter may be moved in six degrees of freedom.

See also col. 9, l. 59 - col. 10, l. 2 and col. 4, l. 35 – col. 5, l. 9 and col. 5, l. 51-57

Therefore, since the catheter can be manipulated in six degrees of freedom and the position information is relayed back to the user for any position that the catheter is in, it would be obvious that the system is capable of providing position information in all six degrees of freedom.

Stevens-Wright teach a steerable catheter with a thumb control (see fig. 1, ref. number 92).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate a position sensor in or on the distal tip of the catheter and to provide a thumb control in the invention of Plicchi et al., in light of the teachings of Funda et al. or Stevens-Wright, in order to enhance the utility of the device.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3737

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRYSTAL I. LEACH whose telephone number is (571)272-5211. The examiner can normally be reached on Monday through Friday, 8 am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737

/Crystal I Leach/

Application/Control Number: 10/785,162

Page 8

Art Unit: 3737

Examiner, Art Unit 3737